Leave Blank
PROPOSAL #_____
APPROVAL DATE_____
EXPIRATION DATE_____

NATIONAL INSTITUTES OF HEALTH

ANIMAL STUDY PROPOSAL
(Revised 11/99)
(See NIH Manual 3040-2)

PLEASE TYPE

A. ADMINISTRATIVE DATA:

Institute or Center:

Principal Investigator:
Building/Room:
Telephone:
FAX:
Email:

Division, Laboratory, or Branch:

Project Title:

Initial Submission [ ]; Renewal [ ] or Modification [ ] of Proposal Number

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e. Co-investigator(s)):

All personnel working with animals must take the appropriate animal course from OACU and must be enrolled in the Animal Exposure Surveillance Program through Occupational Medical Services.

B. ANIMAL REQUIREMENTS:

Species: Age/Weight/Size: Sex:

Stock or Strain: Source(s):

Holding Location(s): Animal Procedure Location(s):
Number of Animals:

Year 1	Year 2	Year 3	=	TOTAL

C. TRANSPORTATION: Transportation of animals must conform to all NIH and Facility guidelines/policies. If animals will be transported between facilities, describe the methods and

containment to be utilized. If animals will be transported within the Clinical Center, also include the route and elevator(s) to be utilized.

D. STUDY OBJECTIVES: Briefly explain in **NON-TECHNICAL TERMS** the aim of the study and how the study may benefit human or animal health or advance scientific understanding of biological processes.

E. RATIONALE FOR USE OF ANIMALS:

1) Explain your rationale for animal use.
2) Justify the appropriateness of the species selected.
3) Justify the number of animals to be used. Please provide a **detailed** justification for the number of animals used. The number of animals to be used in each part of the study should be stated. Justification can include statistical analysis and published numbers. As per the 08/21/2000 letter to investigators, all animal studies must be classified (and stated) in the justification as a: Teaching protocol, Tissue Procurement Protocol, Holding Protocol, Pilot Study or Clinical Studies. Please The CC Biostatistics and Clinical Epidemiology Service must review all Clinical Studies and sign off in Section O. Some Pilot Studies will also need to be reviewed; please see the APD for further assistance.

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: Briefly explain the experimental design and specify all animal procedures. **THIS DESCRIPTION SHOULD ALLOW THE ACUC TO UNDERSTAND THE EXPERIMENTAL COURSE OF AN ANIMAL FROM ITS ENTRY INTO THE EXPERIMENT TO THE ENDPOINT OF THE STUDY.** Specifically address the following:

(Use additional sheets if necessary.)

-**Injections or Inoculations** (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules)
-**Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology)
-**Non-survival surgical procedures (Provide details of survival surgical procedures in Section G.)**
-**Radiation** (dosage and schedule)
-**Methods of restraint** (e.g., restraint chairs, collars, vests, harnesses, slings, etc.),
-**Animal Identification Methods** (e.g., ear tags, tattoos, collar, cage card, etc
- **Other procedures** (e.g., survival studies, tail biopsies, etc.).

-Resultant Effects, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.).

-Experimental Endpoint Criteria (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

G. SURVIVAL SURGERY: If proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized. **(Use additional sheets if necessary.)**

2. Who will perform surgery and what are their qualifications and/or experience?:

3. Where will surgery be performed, Building and Room? __

4. Describe post-operative care required, including consideration of the use of post-operative analgesics, and identify the responsible individual:

5. Has major survival surgery been performed on any animal prior to being placed on this study Y/N. If yes, please explain:

6. Will more than one major survival surgery be performed on an animal while on this study? Y/N. If yes, please justify:

H. PAIN OR DISTRESS CATEGORY: The ACUC is responsible for applying U.S. Government Principle IV. Contained in Appendix 3: "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." Check the appropriate category(ies) and indicate the approximate number of animals in each. Sum(s) should equal total from Section B.

IF ANIMALS ARE INDICATED IN COLUMN E, A SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR

TRANQUILIZERS DURING AND/OR FOLLOWING PAINFUL OR DISTRESSFUL PROCEDURES IS CONTRAINDICATED. PLEASE COMPLETE THE EXPLANATION FOR COLUMN E LISTINGS FORM AT THE END OF THIS DOCUMENT. THIS FORM WILL ACCOMPANY THE NIH ANNUAL REPORT TO USDA. Note: THIS COLUMN E FORM, AND ANY ATTACHMENTS, e.g., THE ASP, ARE SUBJECT TO THE FREEDOM OF INFORMATION ACT.

			NUMBER OF ANIMALS USED EACH YEAR		
			Year 1	Year 2	Year 3
	USDA Column C	Minimal Transient, or No Pain or Distress			
	USDA Column D	Pain or Distress Relieved By Appropriate Measures**			
	USDA Column E	Unrelieved Pain or Distress **			

Describe your consideration of alternatives to procedures listed for Column D and E that may cause more than momentary or slight pain or distress to the animals, and your determination that alternatives were not available. [Note: Principal Investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] Delineate the methods and sources used in the search below. Data base references must include databases searched (2 or more), the date of the search, period covered, and keywords used:

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION: For animals indicated in Section H, Column D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration.

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: (1) Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If methods of euthanasia include those not recommended by the AVMA Panel on Euthanasia, provide justification why such methods must be used. (2) Indicate the method of carcass disposal if not as MPW.

K. HAZARDOUS AGENTS: Use of hazardous agents requires the approval of an ICD safety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens may be attached at the discretion of the ACUC.

	YES	NO	LIST AGENTS AND REGISTRATION DOCUMENT NUMBER (IF APPLICABLE)
1. Radioisotopes			
2. Biological Agents			
3. Hazardous Chemicals or Drugs			
4. Recombinant DNA			

Study conducted at Biosafety Level

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Use of volatile anesthetics requires a description of scavenging methods used. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS: (e.g., cell lines, antiserum, etc.)

1. Specify Material :

2. Source: Material Sterile or Attenuated: ___ Yes ___No

3. If derived from rodents, has the material been MAP/RAP/HAP tested? _____Yes (Attach copy of results) ___ No

4. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP

tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____Initials of Principal Investigator.

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY: List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.). Include justification for exemption from social housing for nonhuman primates or exercise for dogs.

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended an approved NIH Investigator training course.

   Year of Course Attendance: _ Location:
   Year (s) of Refresher Training:
2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.

3. I certify that all individuals working on this proposal are participating in the NIH Animal Exposure Surveillance Program.

4. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal have attended the course "Using Animals in Intramural Reserch: Guidelines for Animal Users" and will complete refresher training as required, and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); procedures for reporting animal welfare concerns.

5. **FOR COLUMN D AND COLUMN E PROPOSALS (see section H):** I certify that I have reviewed the pertinent scientific literature and the sources and or databases (2 or more) as noted in paragraph H, and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.

6. I will inform the ACUC of any proposed significant changes in this study.

Principal Investigator: Signature _____ Date: _____

O. CONCURRENCES:

Clinical Center Biostatistics and Clinical Epidemiology Service certification of statistical review, required for Clinical Studies and selected Pilot Studies.

Signature_____ Date_____

Laboratory/Branch Chief certification of review and approval on the basis of scientific merit. Scientific Director's signature required for proposals submitted by a Laboratory or Branch Chief.

Name____ Signature_____Date_____

Safety Representative certification of review and concurrence. (Required of all studies utilizing hazardous agents.)

Name____ Signature_____Date_____

Facility Manager certification of resource capability in the indicated facility to support the proposed study.

Facility _____ Name ___ Signature_____Date_____

Facility ___ Name ____ Signature_____Date_____

Facility ___ Name _____ Signature_____Date_____

Facility ____ Name _____ Signature_____Date_____

COMMENTS:

Facility Veterinarian certification of review.

Name ____ Signature_____Date_____

Attending Veterinarian certification of review.

Name ___ Signature_____Date_____

P. FINAL APPROVAL: Certification of review and approval by the **Clinical Center** Animal Care and Use Committee Chairperson.

CHAIRPERSON ___ Signature_____Date_____